I. Amendments to the Claims

This listing of claims shall replace all prior versions, and listings, of claims in the application.

Listing of Claims

Claim 1. (Currently Amended) A controlled release oral dosage form for the reduction of serum glucose levels in human patients with NIDDM, comprising an effective dose of metformin ~~at least one suitable antihyperglycemic drug~~ or a pharmaceutically acceptable salt thereof and a controlled-release carrier, said dosage form being suitable for providing once-a-day oral administration of the drug or pharmaceutically acceptable salt thereof, wherein the dosage form provides a mean time to maximum plasma concentration (T_{max}) of the drug from 5.5 to 7.5 hours after administration following dinner.

Claims 2-3. (Cancelled)

Claim 4. (Original) The controlled release oral dosage form of claim 1, which provides a mean time to maximum plasma concentration (T_{max}) of the drug from 6.0 to 7.0 hours after the administration of the dose.

Claim 5. (Previously presented) The controlled release oral dosage form of claim 1, which provides a mean time to maximum plasma concentration (T_{max}) of the drug from 5.5 to 7.0 hours after the administration of the dose.

Claim 6. (Previously presented) The controlled release oral dosage form of claim 1, which provides a mean time to maximum plasma concentration (T_{max}) of the drug from about 6.0 to 7.5 hours after the administration of the dose.

Claim 7. (Original) The controlled release oral dosage form of claim 1, which exhibits the following dissolution profiles when tested in a USP type 2 apparatus at 75 rpm in 900 ml of simulated intestinal fluid (pH 7.5 phosphate buffer) and at 37 C:
0-30% of the drug is released after 2 hours;
10-45% of the drug is released after 4 hours;
30-90% of drug is released after 8 hours;
not less than 50% of the drug is released after 12 hours;
not less than 60% of the drug is released after 16 hours; and
not less than 70% of the drug is released after 20 hours.

Claim 8. (Original) The controlled release oral dosage form of claim 1, which exhibits the following dissolution profiles when tested in a USP type 2 apparatus at 75 rpm in 900 ml of simulated intestinal fluid (pH 7.5 phosphate buffer) and at 37 C:
0-25% of the drug is released after 2 hours;
20-40% of the drug is released after 4 hours;
45-90% of the drug is released after 8 hours;
not less than 60% of the drug is released after 12 hours;
not less than 70% of the drug is released after 16 hours; and
not less than 80% of the drug is released after 20 hours.

Claim 9. (Original) The controlled release oral dosage form of claim 1, which provides a width at 50% of the height of a mean plasma concentration/time curve of the drug from about 4.5 to about 13 hours.

Claim 10. (Original) The controlled release oral dosage form of claim 1, which provides a width at 50% of the height of a mean plasma concentration/time curve of the drug from about 5.5 to about 10 hours.

Claim 11. (Currently Amended) The controlled release oral dosage form of claim ~~3~~ 1, which provides a mean maximum plasma concentration (C_{max}) of metformin which is more than about 7 times the mean plasma level of said metformin at about 24 hours after the administration.

Claim 12. (Currently Amended) The controlled release oral dosage form of claim ~~3~~ 1, which provides a mean maximum plasma concentration (C_{max}) of metformin which is from about 7 times to about 14 times the plasma level of said metformin at about 24 hours after administration.

Claim 13. (Currently Amended) The controlled release oral dosage form of claim ~~3~~ 1, which provides a mean maximum plasma concentration (C_{max}) of metformin which is from about 8 times to about 12 times the plasma level of said metformin at about 24 hours after administration.

Claim 14. (Currently Amended) The controlled release oral dosage form of claim ~~3~~ 1, which provides a mean maximum plasma concentration (C_{max}) of metformin from about 1500 ng/ml to about 3000 ng/ml, based on administration of a 2000 mg once-a-day dose of metformin.

Claim 15. (Currently Amended) The controlled release oral dosage form of claim ~~3~~ 1, which provides a mean maximum plasma concentration (C_{max}) of metformin from about 1700 ng/ml to about 2000 ng/ml, based on administration of a 2000 mg once-a-day dose of metformin.

Claim 16. (Currently Amended) The controlled release oral dosage form of claim ~~3~~ 1, which provides a mean $AUC_{0\text{-}24hr}$ of at least 80% of the mean $AUC_{0\text{-}24}$ provided by administration of an immediate release reference standard twice a day, wherein the daily dose of the reference standard is substantially equal to the once-a-day dose of metformin administered in the controlled release oral dosage form.

Claim 17. (Currently Amended) The controlled release oral dosage form of claim ~~3~~ 1, which provides a mean $AUC_{0\text{-}24hr}$ of at least 90% of the mean $AUC_{0\text{-}24}$ provided by administration of an

immediate release reference standard twice a day, wherein the daily dose of the reference standard is substantially equal to the once-a-day dose of metformin administered in the controlled release oral dosage form.

Claim 18. (Currently Amended) The controlled release oral dosage form of claim ~~3~~ 1, which provides a mean $AUC_{0\text{-}24hr}$ from about 17200 ng.hr/ml to about 33900 ng.hr/ml, based on administration of a 2000 mg once-a-day dose of metformin.

Claim 19. (Currently Amended) The controlled release oral dosage form of claim ~~3~~ 1, which provides a mean $AUC_{0\text{-}24hr}$ from about 17200 ng.hr/ml to about 26500 ng.hr/ml, based on administration of a 2000 mg once-a-day dose of metformin.

Claim 20. (Currently Amended) The controlled release oral dosage form of claim ~~3~~ 1, which provides a mean $AUC_{0\text{-}24hr}$ from about 19800 ng.hr/ml to about 33900 ng.hr/ml, based on administration of a 2000 mg once-a-day dose of metformin.

Claims 21-27. (Cancelled)

Claim 28. (Previously presented) The controlled release oral dosage form of claim 9, which provides a mean time to maximum plasma concentration (T_{max}) of metformin from 6.0 to 7.5 hours after administration.

Claim 29. (Currently Amended) The controlled release oral dosage form of claim ~~3~~ 1, wherein the metformin is provided by at least one controlled-release tablet, said tablet comprising:

(a) a core comprising:
  (i) the metformin or a pharmaceutically acceptable salt;
  (ii) optionally a binding agent; and
  (iii) optionally an absorption enhancer;
(b) a membrane coating surrounding the core; and
(c) at least one passageway in the membrane.

Claim 30. (Original) The controlled release oral dosage form of claim 29, wherein said membrane is a semipermeable membrane.

Claims 31-42. (Cancelled)